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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,683	07/16/2001	Jamie M. Grooms	197319US/222962US	4376

7590 03/15/2006

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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,683	GROOMS ET AL.	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *111-118 and 120-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *111-118, 120-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed April 18, 2005, have been fully considered.

The provisionally provisional double patenting rejection under 35 U.S.C. 101 as claiming the same invention as that of all claims of copending Application No. 10/375,540 has been withdrawn; 10/375,540 has been abandoned.

Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Albee (Bone Surgery with Machine Tools), applicant has amended claim 1 to include a "circular" through hole which is shown in at least figure 3, sub-figure 10 of Albee. Applicant has also amended claim 1 to include the limitation "*said assembled bone implant being suitable for implantation into said patient*". It is the Examiner's position that the assembled bone portions of Albee are capable of being used as a donor tissue and implanted into a second patient which fulfills all functional language. MPEP 2114 teaches:

> **APPARATUS CLAIMS MUST BE STRUCTUR-ALLY DISTINGUISHABLE FROM THE PRIOR ART**
>
> >While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. >*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997
>
> **MANNER OF OPERATING THE DEVICE DOES NOT DIFFERENTIATE APPARATUS CLAIM FROM THE PRIOR ART**
>
> A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)

As previously stated by the Examiner, additionally, in situations of multiple breaks, it is conceivable that bone portions are connected together outside of the body and than placed back, such as skull fractures.

Regarding the D-shape limitation, it is the Examiner's position that D-shape is not limited to including a D-shape hole. The Examiner knows of that D-shape is used to describe the head of a nail (for a nail gun) which does not have a hole. The Examiner suggests adding the limitation to the claims.

Note figure 3, sub-figures 1, 2a 10, 11, 12, 15 which are interpreted as having through holes. Note the holes of sub-figures 11-12 extend through the front to back. The Examiner notes applicant's arguments regarding some of the figures are joinery techniques. However, Albee is teaching these can be used with bone. Referring to at least figure 3, sub-figure 15, it is unclear why applicant does not believe this is bone, however, it is clear to one having ordinary skill in the art interpreting the teachings of Albee, that this could be bone.

Claim 126, requires at the first and second portions being superimposed to form a D-shape, which is not taught or shown in figure 3, sub-figures 11-12.

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030), applicant's argument is not fully understood nor persuasive. Coates et al, despite the difficulty of manufacturing, teaches a D-shaped cortical bone implant:

(31) The spacers of this invention are preferably formed of a bone composition or material. The bone may be autograft, allograft, xenograft or

any of the above prepared in a variety of ways. Cortical bone is preferred for its compressive strength. In one embodiment, the spacers are obtained as a cross sectional slice of a shaft of a long bone. For example, various shaped spacers may be obtained by machining a cortical ring into the desired configuration. The exterior surfaces of the walls can be formed by machining the ring to a D-shape.

It is the Examiner's position that it would have been obvious to one having ordinary skill in the art to have used the teaching of Siebels and have stacked the device of Coates to **adjustably** build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon. This combination has nothing to do with how easy or difficult it is to build either implant of Siebels and Coates; and applicant's arguments are spurious. It is noted that in page 16, second paragraph, applicant addresses the combination of Coates and Brantigan under Section III Coates over Siebel; in response to this Office action, please keep arguments to separate rejections separate.

As pervious stated:

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030), applicant argues that Siebels teaches connecting (stacking) implant portions because it is easier to manufacture. In response to applicant's argument, the fact that Siebels recognized another advantage of their invention does not take away from the teaching and advantage of multiple portions stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Brantigan (5,192,327) in view of Coates et al (5,989,289), applicant's arguments are not persuasive.

Regarding the amendment to claim 111 including "circular through hole", circular is defined as "of or relating to a circle". Elements 14 and 24 are interpreted as being circular. Additionally, the entire opening can be interpreted as the through hole.

The Examiner notes that Brantigan does not teach cortical bone, the typo has been resolved.

Regarding the applicant's section 1., applicant argues that Brantigan teaches away from the use of metals. However, the abstract states:

> The annular implants have ample spaces to allow ingrowth of blood capillaries and packing of bone graft and are preferably made of a radiolucent material, preferably biocompatible carbon fiber reinforced polymers **or are alternately made of traditional orthopaedic implant materials such as nickel, chromium, cobalt, stainless steel or titanium.**

Again, Coates **specifically** states that the implant of Brantigan is flawed because the materials used (**including** metals) of Brantigan are too stiff which causes stress shielding, etc., as stated in the grounds of rejection. Coates in the very next paragraph teaches bone as an implant material "avoid[s] the disadvantages of metal implants"; see column 2, lines 49 et seq. It is also noted that polymeric material taught by Brantigan is foreign to the body and that *foreign bodies [which] can never be fully incorporated into the fusion mass.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 111-118, 120-123, 129-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Albee (Bone Surgery with Machine Tools).

Referring to all figures, specifically figure 3, sub-figures 10-12 and 15, Albee teaches:

a first cortical bone portion;

a second cortical bone portion;

said first cortical bone portion and said second cortical bone portion having one or more (circular shown in at least figure 3, sub-figure 10) through holes sized and positioned for receiving one or more retention pins for

connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant unitary body outside the patient and suitable for implantation into said patient.

Note figure 3, subfigures 1, 2a 10, 11, 12, 15 which are interpreted as having through holes.

Albee teaches the pines are grafts which inherently comprise cortical and cancellous bone.

Regarding claim 116, mirror image, see at least sub-figure 15.

Regarding claim 121, the embodiments shown in sub-figures 11-12 are sized and shaped for in the form of a cervical implant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 111-118 and 120-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030).

Referring to all figures, Coates teaches a D-shaped cortical bone spinal implant (see column 11, lines 42 et seq.). However, Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin. Siebels also teaches a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Siebels to stack and connect individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Regarding at least claims 114-115, 123, and 127, lacking any criticality in the specification, the use of the claimed materials such as titanium in lieu of those taught by Seibels produce no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claim 122, see column 11, lines 62 et seq.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Claims 111-118 and 120-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (5,192,327) in view of Coates et al (5,989,289).

Referring to all figures, specifically figures 2 and 5, Brantigan teaches a D-shaped bone implant comprising:

a first portion 21;

a second portion 21;

said first portion and said second portion having one or more through holes 24 sized and positioned for receiving one or more retention pins 15 for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first portion to said second portion to form said assembled bone implant unitary body.

However, Brantigan fails to teach the first and second portions are cortical bone. Brantigan teaches the device can be made of traditional orthopaedic implant materials; see the abstract. Coates et al teaches a D shaped implant can be made of cortical bone. It would have been obvious to one having ordinary skill in the art to have utilized cortical bone which is a traditional orthopaedic implant material as taught by Coates for any of the elements of Brantigan because "*5,192,327 to Brantigan teach hollow metal cage structures. Unfortunately, due to the stiffness of the material, some metal implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. Metal devices are also foreign bodies which can never be fully incorporated into the fusion mass.*" See column 2, lines 40 et seq. of Coates. Additionally, "cortical bone with the advantage of incorporation of the spacer material without stress shielding."

Regarding the amendment to claim 111 including "circular through hole", circular is defined as "of or relating to a circle". Elements 14 and 24 are interpreted as being circular. Additionally, the entire opening can be interpreted as the through hole.

Regarding at least claims 114-115, 123, and 127, the combination at least teaches titanium or cortical bone, lacking any criticality in the specification, the use of the specific use of any claimed materials for the pin in lieu of those taught by references produces no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER